

**REMARKS**

**Amendments**

In the interest of expediting the prosecution of this Application, Applicant amends Claims 1, 5-6, 17, 19-28, 32-44 and 47-48. Applicant amends Claims 1, 5-6, 17, 19-28, 32-44 and 47-48 in order to further clarify the subject matter claimed. Applicant reserves the right to reintroduce the original Claims 1, 5-6, 17, 19-28, 32-44 and 47-48 in one or more continuation-type application.

Claim 1 is amended to delete “and an active agent selected from” and “optionally”. Support for the amendment is found, for example, from Claim 1 as originally filed.

Claim 5-6 are amended to replace “active agent” with “dehydroepiandrosterone, or pharmaceutically or veterinarily acceptable salt thereof, or a ubiquinone or pharmaceutically or veterinarily acceptable salt thereof”. Support for the amendment is found, for example, from Claims 1 and 5-6 as originally filed.

Claims 16 and 49-79 are withdrawn as directed to a non-elected invention.

Claims 19-28, 32-44 and 47-48 are amended to replace “formulation” with “composition”. Support for the amendment is found, for example, from Claims 1, 19-28, 32-44 and 47-48 as originally filed.

Claim 27 is amended to delete “other therapeutic agents”. Support for the amendment is found, for example, from Claim 27 as originally filed.

Claim 28 is amended to delete “which may further comprise suspending agents or thickening agents”. Support for the amendment is found, for example, from Claim 28 as originally filed.

Claim 41 is amended so that Claim 41 depends from Claim 15 instead of Claim 16. Support for the amendment is found, for example, from Claim 41 as originally filed.

**Response**

Claims 1-15 and 17-48 are pending in the present application.

Claims 16 and 49-79 are withdrawn.

**1. 35 U.S.C. 112, second paragraph.**

The Examiner rejects Claims 5-6, 17, 19-28 and 32-48 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleges that the expression “active agent” is unclear. The expression “active agent” in Claims 5-6 is replaced with the phrase “dehydroepiandrosterone, or pharmaceutically or veterinarily acceptable salt thereof, or a ubiquinone or pharmaceutically or veterinarily acceptable salt thereof”. Since the alleged unclear expression is replaced, the Examiner is respectfully requested to withdraw this basis of rejection.

The Examiner alleges that the expression “other therapeutic agents” is indefinite. The expression “other therapeutic agents” in Claim 17 is deleted. Since the alleged indefinite expression is deleted, the Examiner is respectfully requested to withdraw this basis of rejection.

The Examiner alleges that the limitation “formulation” has insufficient antecedent basis. The term “formulation” in Claims 19-28 and 32-41 is replaced with the term “composition”. Since the term “composition” has sufficient antecedent basis, the Examiner is respectfully requested to withdraw this basis of rejection.

The Examiner alleges that the limitation “the kit” in Claims 42-48 has insufficient antecedent basis “since claim 16 is drawn to the method and claim 15 is drawn to the composition” (page 4, lines 2-3). Applicants respectfully point out that Claims 43-48 depend, directly or indirectly, from Claim 42. Claims 42-48 recite the term “The kit”. Amended Claim 42 recites: “A kit comprising the composition of claim 15, and a delivery device.” Claim 15 is a composition claim depending from Claim 1. Therefore, there is sufficient antecedent basis for the term “The kit” in Claims 42-48. Thus, the Examiner is respectfully requested to withdraw this basis of rejection.

**2. Double Patenting**

The Examiner rejects Claims 1-15 and 17-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789. Applicants will submit a properly executed Terminal Disclaimer to overcome this rejection when there are any otherwise allowable claims.

**3. 35 U.S.C. § 103(a)**

The Examiner rejects Claims 1-15 and 17-48 under 35 U.S.C. § 103(a) as allegedly being obvious over Prendergast (U.S. Patent No. 4,956,355). Amended Claims 1-15 and 17-48 are directed to a composition, or kit, comprising a DHEA having the chemical formula (I) **and a ubiquinone**. Prendergast disclose the use of DHEA for the prophylaxis and therapy of retroviral infection. Prendergast does not disclose the use of ubiquinone. The Examiner has stated that "Prendergast does not expressly disclose that the composition optionally further comprises the particular antioxidant herein, ubiquinone." (page 6, lines 20-22).

MPEP 2143.3 states: "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested in the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." Ubiquinone is neither taught nor suggested by Prendergast.

The Examiner argues that "One having ordinary skill in the art at the time the invention was made would have been motivated to optionally further employ the particular antioxidant herein, ubiquinone, in the composition of Prendergast since ubiquinone herein are well known antioxidant, coenzyme Q10, and adding a well known antioxidant to a composition is considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art." (page 7, lines 13-18; emphasis in the original). The only reasoning the Examiner provides to demonstrate that the addition of ubiquinone to the composition is obvious is that "**adding a well known antioxidant to a composition is considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art**". The Examiner does provide any evidence in the record to support the allegation that adding a well known antioxidant to a composition is considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art. The court in *In re Zurko* (59 USPQ2d 1693 (Fed. Cir. 2001)) held that: "With respect to core factual findings in a determination of patentability . . . the Board cannot simply reach conclusions based on its own understanding or experience -- or on its assessment of what would be basic knowledge or common sense. Rather, the Board **must point to some concrete evidence in the record in support of these findings**." (emphasis added; *id.* at 1697). In this present application, Applicant respectfully point out **the Examiner has not**

**pointed to any concrete evidence in the record in support of the Examiner's allegation regarding ubiquinone.** Therefore the Examiner has not made a prima facie case of obviousness.

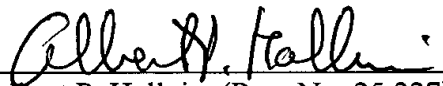
Since a prima facie case of obviousness has not been made for Claims 1-15 and 17-48, the Examiner is respectfully requested to withdraw this rejection.

**CONCLUSION**

In view of the foregoing amendment and remarks, the Applicant believes that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 463-8109.

Respectfully submitted,

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